

REMARKS

Applicants have previously requested the title be amended. However, since no mention of this request was made by the Examiner, Applicants have resubmitted the request herewith. The title is being amended to more accurately reflect the elected invention.

Claim 24 has been amended to remove the word “about” in the phrase “at least about 90% identical” in part (c).

Claim 25 has been amended to replace SEQ ID NO’s 38 and 43, which are nucleic acid sequences, with SEQ ID NO’s 39 and 44, which represent the corresponding amino acid sequences.

Claims 27 and 28 have been amended to remove the word “sequence” from the phrase “nucleic acid sequence molecule” in parts (c). Applicants believe this amendment clarifies the language of the claim.

Claim 28 was also amended to replace the word “sequences” in the phrase “has a nucleic acid sequences” with the word “sequence”.

Applicants submit that no new matter has been entered into the specification.

I. Claim Objections

The Examiner has objected to claim 28 stating that in part (c), the phrase “has a nucleic acid sequences” should be changed to “has a nucleic acid sequence”. Applicants note that the appropriate correction has been made.

II. Rejection Under 35 U.S.C. §112, second paragraph

The Examiner has rejected claims 24, 25 and 27 as being vague, indefinite, misdescriptive and inaccurate.

The Examiner states the recitation of “at least about” in claim 24(c) is vague and indefinite. While Applicants disagree with the Examiner’s position, in the interest of expediting prosecution, the word “about” has been removed from the language of claim 24(c).

The Examiner further states that the recitation of “having the amino acid sequence of SEQ ID NO:38 or SEQ ID NO:43” in claims 25(a) and 25(b) is misdescriptive and inaccurate since SEQ ID NO’s 38 and 43 are nucleic acid sequences and not peptides. Applicants note claims 25 and 26 have been amended so SEQ ID NO’s 38 and 43 have been replaced with SEQ ID NO’s 39 and 44, respectively, which represent the corresponding amino acid sequences.

Finally the Examiner states that the recitation of “said isolated nucleic acid sequence molecule comprises SEQ ID NO:38 or SEQ ID NO:43” in claims 27(c) and 28(c) is misdescriptive and inaccurate since SEQ ID NO’s 38 and 43 are nucleic acids and not peptides. Applicants’ understanding of this rejection is that the Examiner’s interpretation of the quoted phrase is that “nucleic acid sequence molecule” refers to a peptide. Applicants note the word “sequence” was inadvertently included in the phrase. Claims 27 and 28 have been amended so the phrase now reads “said isolated nucleic acid molecule comprises SEQ ID NO:38 or SEQ ID NO:43” which Applicants believe is accurate.

III. Rejections Under 35 U.S.C. §103(a) – obviousness

The Examiner has rejected 22-25, 27-33, 43, 44, 46 and 47 as being unpatentable over Foss et al. in view of Applicants admitted state of the prior art (e.g., instant application at pages 3-4). Specifically, the Examiner states that Foss et al. teach the construction of an expression vector containing the coding sequences for porcine IL-12 p35 and p40 subunits. The subunit coding sequences are joined by a linker. The Examiner also states the instant application acknowledges that the feline IL-12 p35 and p40 subunit coding sequences are old. The Examiner therefore concludes that it would have been obvious for one of skill in the art to substitute the known feline sequences for the porcine sequences of Foss et al. in order to express a single chain feline IL-12 protein. Applicants traverse the rejection and request reconsideration based on the following remarks.

First, it is well established that for a *prima facie* case of obviousness to exist the cited reference(s) must provide clear and particular teaching which would motivate one of ordinary skill in the art to make the suggested combination. The Federal Circuit has held such teaching to be an “essential evidentiary component of an obviousness holding.” *C.R. Bard Inc. V. M3 Systems Inc.*, 48 USPQ2d 1225, 1232 (Fed. Cir., 1998). Additionally, the court has stated “this showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not evidence.” *Brown and Williamson Tobacco Corp. v. Phillip Morris Inc.*, 56 USPQ2d 1546, 1459 (Fed. Cir., 2000) Applicants believe the references cited by the Examiner in the instant application lack the required, clear and particular teaching which would motivate one of ordinary skill in the art to make the suggested combinations.

Foss et al. teach the expression of a single chain, porcine IL-12 protein in which the p35 and p40 subunits are connected by a linker. However, Foss et al. is solely concerned with

porcine IL-12, and does not teach or suggest the desirability of expressing IL-12 from any other animal, in particular, felines. Furthermore, the only other teaching cited by the Examiner is the Applicant's own specification, in particular those sections stating that the sequences of the feline IL-12 p35 and p40 subunits were known in the prior art. It is notable that the Examiner does not cite the feline IL-12 prior art directly as providing the suggestion to express feline IL-12 as a single chain protein. Thus the only nexus between the feline IL-12 sequences and the expression of IL-12 as a single chain protein is Applicants disclosure. Applicants contend that the Examiner's use of the instant disclosure as a roadmap to combine the prior art is a clear case of hindsight reconstruction. Moreover, Applicants assert that the use of such reconstruction has been held to be improper by the Federal Circuit. (See, for example, *In re Rouffet*, 149 F.3d 1350, 1355-56 [47 USPQ2d 1453] (Fed. Cir. 1998). ... "section 103 requires some suggestion or motivation, before the invention itself, to make the new combination.") Thus, in view of the failure of the cited prior art reference to teach the desirability of the suggested combination, and the Examiner's reliance on hindsight reconstruction to reach the instant invention, Applicants contend the Examiner has failed to establish a case of prima facie obviousness.

Next, even if Foss et al. is combinable with the known feline IL-12 sequences, which Applicants disagree, Applicants contend that, at best, the combination does not render the invention obvious, but rather "obvious to try".

Applicants liken the facts in the instant Application to those in *Ex parte Primakoff*, 64 USPQ2d 1848 (BdPatApp & Int 2001). In *Primakoff*, Appellants were claiming a method of contraception in a non-Cavia porcellus (guinea pig) mammal, the method comprising immunizing the mammal with purified sperm protein PH-20 from the specie of animal being immunized. Appellants own previous work (the Prior Art) had already shown that immunization of guinea pigs with guinea pig PH-20 resulted in 100% effective contraception. The Prior Art also stated the human analogue of PH-20 would be a candidate for a contraceptive immunogen in humans. The Examiner rejected the claims concluding that, since the guinea pig PH-20 protein had been shown to be effective as a contraceptive immunogen, Appellants claimed method of using PH-20 in other species as a contraceptive immunogen was obvious. On Appeal, the USPTO Board of Patent Appeals and Interferences (BPAI) reversed the rejection, holding the disclosure of the Prior Art did not make the appealed claims obvious, but rather, presented a classic obvious to try situation. The BPAI concluded that the Prior Art, in stating that similar work could be attempted in humans, merely provided a general disclosure which although might pique a scientists

curiosity to experiment further in the area of human immunization, did not provide sufficient teaching as to how to obtain the desired result or that the claimed result would be obtained. According to the Board, "This is the definition of obvious to try."

Applying *Primakoff* to the instant Application, Applicants contend that expression by Foss et al. of porcine IL-12 in a single chain form is analogous to the guinea pig vaccinations in the Prior Art in *Primakoff*; it represents general disclosure which, at most, may stimulate a scientist's interest to experiment further in the area of single chain protein expression. However, Foss et al. does not provide sufficient teaching that the claimed result (i.e., active protein) would be obtained. Moreover, while the Prior Art in *Primakoff* even suggested the disclosed method might be applicable in other species, no such suggestion is present in Foss et al. Thus Applicants maintain the findings in *Primakoff* support their contention that the cited prior art represents a classic "obvious to try" situation. In view of this conclusion, Applicants request withdrawal of the obviousness rejection.

CONCLUSION

All of the claims are believed to be in condition for allowance. The Examiner is invited to contact the undersigned should any issues remain.

Respectfully submitted,

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